

PATENTS Docket No. NaPro-18

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Kmiec et al.

Application No.: 10/681,074 Confirmation No.:7677

Filed : October 7, 2003

For : METHODS AND COMPOSITIONS FOR REDUCING

SCREENING IN OLIGONUCLEOTIDE-DIRECTED

NUCLEIC ACID SEQUENCE ALTERATION

Group Art Unit: 1645

Hon. Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure Statement in the above-identified application. This Statement is submitted:

- [] within three months of the application filing date;
- [X] more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this

Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

19 FG3 2004

Daniel M. Becker

Registration No. 38,376 Attorney for Applicants

FISH & NEAVE Customer No. 1473 1251 Avenue of the Americas New York, New York 10020-1104 Tel.: (650) 617-4000

I hereby Certify that this Correspondence is being Deposited with the U.S. Postal Service as First Class Mail in an Envelope Addressed to : HOM. COMMISSIONER FOR PATEMYS, P.O. BOX 1450, Alexandria, VA 22313-1450 on:

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Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicants hereby make the following documents of record in the above identified application:*

U.S. Patents and Patent Publications

6,573,046	06/03/03	Kmiec et al.
6,479,292	11/12/02	Metz et al.
6,303,376	10/16/01	Glazer
6,271,360	08/07/01	Metz
6,268,490	07/31/01	Imanishi et al.
6,136,601	10/24/00	Meyer
6,043,060	03/28/00	Imanishi
6,004,804	12/21/99	Kumar

^{*} Applicants reserve the right to challenge the status of any of the cited documents as prior art.

5,962,426	10/05/99	Glazer
5,955,363	09/21/99	Lewis
5,912,340	06/15/99	Kutyavin
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5,871,984	02/16/99	Kmiec
5,801,154	09/01/98	Baracchini
5,795,972	08/18/98	Kmiec
5,780,296	07/14/98	Holloman et al.
5,776,744	07/07/98	Glazer et al.
5,760,012	06/02/98	Kmiec et al.
5,756,325	05/26/98	Kmiec
5,731,181	03/24/98	Kmiec
5,565,350	10/15/96	Kmiec
5,422,251	06/06/95	Fresco
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US 2002/0119570	08/29/02	Yoon

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WO	03/075856	09/18/03	PCT
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□rum et al., "Detection of the factor V Leiden mutation by direct allele-specific hybridization of PCR amplicons to photoimmobilized locked nucleic acids," Clinical Chemistry 45(11): 1898-1905 (1999)

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Pursuant to the PTO's waiver of the requirement under 37 CFR 1.98 (a)(2)(i), 1276 OG 55, applicants have not submitted copies of each cited U.S. patent and each U.S. patent application publication. Copies of the aforementioned foreign patent publications and other documents, which are listed on the accompanying Form PTO-1449, are enclosed herewith.

It is respectfully requested that these documents be (1) fully considered by the Patent and Trademark Office during the examination of this application; and (2) printed on any patent that may issue on this application.

Applicants request that a copy of Form PTO-1449, as considered and initialed by the Examiner, be returned with the next communication.

An early and favorable action is respectfully requested.

19FEB 2904

Daniel M. Becker

Respect Aul/Iy

Registration No. 38, 376 Attorney for Applicants

FISH & NEAVE

Customer No. 1473

1251 Avenue of the Americas New York, New York 10020-1104

submitted.

Tel.: (650) 617-4000

I hereby Certify that thi Correspondence is being Deposited with the U.S. Postal Service as First Class Mail in an Envelope Addressed to : HOM. COMMISSIONER FOR PATEMYS, P.O. BOK 1450, Alexandria,

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO. NaPro-18	SERIAL NO. 10/681,074
APPLICANT Eric B. Kmiec et al.	
FILING DATE October 7, 2003	GROUP 1645

47U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF
	6,573,046	06/03/03	Kmiec et al.	 		APPROPRIATE
	6,479,292	11/12/02	Metz et al.	<u>- </u>		
	6,303,376	10/16/01	Glazer			
	6,271,360	08/07/01	Metz			
	6,268,490	07/31/01	Imanishi et al.			
	6,136,601	10/24/00	Meyer			
	6,043,060	03/28/00	Imanishi			
	6,004,804	12/21/99	Kumar			
	5,962,426	10/05/99	Glazer			
	5,955,363	09/21/99	Lewis			
	5,912,340	06/15/99	Kutyavin			
	5,888,983	03/30/99	Kmiec et al.			
	5,871,984	02/16/99	Kmiec			
	5,801,154	09/01/98	Baracchini			
	5,795,972	08/18/98	Kmiec			
	5,780,296	07/14/98	Holloman et al.			
	5,776,744	07/07/98	Glazer et al.			
	5,760,012	06/02/98	Kmiec et al.			
	5,756,325	05/26/98	Kmiec			
	5,731,181	03/24/98	Kmiec			
	5,565,350	10/15/96	Kmiec			
	5,422,251	06/06/95	Fresco			
	US 2003/0217377	11/20/03	Kmiec et al.			
	US 2003/0051270	03/13/03	Kmiec et al.			
	US 2002/0143952	10/03/02	Sugiarto et al.			
	US 2002/0119570	08/29/02	Yoon			

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FORM PTO-1			F COMMERCE MARK OFFICE	ATTY. DOC NaPro-18	KET NO.	SERIAL N 10/681,07	
		ON DISCLOSUI		APPLICANT Eric B. Kmie			
	STATEMENT		· · · · · · · · · · · · · · · · · · ·	FILING DAT October 7, 2	_	GROUP 1645	
		FOR	EIGN PATENT DOCUI	MENTS			
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSI YES	ATION NO
	WO 03/075856	09/18/03	PCT				
	WO 03/027640	04/03/03	PCT				
	WO 03/027265	04/03/03	PCT				
	WO 03/027264	04/03/03	PCT				
	WO 02/26967	04/04/02	PCT				
	WO 02/10364	02/07/02	PCT				
	WO 01/92512	12/06/01	PCT				
	WO 01/87914	11/22/01	PCT				
	WO 01/73002	10/04/01	PCT				
	WO 01/24615	04/12/01	PCT				
	WO 01/15740	03/08/01	PCT				
_	WO 00/66604	11/09/00	PCT				-
	WO 00/56748	09/28/00	PCT				
	WO 00/51424	09/08/00	PCT				
	WO 00/23567	04/27/00	PCT				
	WO 99/58702	11/18/99	PCT				
	WO 99/14226	03/25/99	PCT				
	WO 98/39352	09/11/98	PCT				Х
	OTHER D	OCUMENTS (I	ncluding Author, Title, I	Date, Pertinen	t Pages, Etc.)		
EXAMINER INITIAL							
	Alexeev et al., "Stable and inheritable changes in genotype and phenotype of albino melanocytes induced by an RNA-DNA oligonucleotide," <i>Nature Biotech.</i> 16:1343-1346 (1998)					es	
	Campbell et al., cells," New Biolo		ecombination involving (1989)	small single-si	tranded oligonu	cleotides in	human
	Chan et al., "Targetethered to a trip	geted correction	n of an episomal gene i onucleotide," <i>J. Biol. C</i>	in mammalian	cells by a short 41-11548 (1999	DNA fragm	ent
	1	lex DNA: funda	mentals, advances, an				" J. Mol.

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FÖRM PTO-1	449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. NaPro-18	SERIAL NO. 10/681,074	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT Eric B. Kmiec et al.		
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EXAMINER INITIAL				
	Chang et al., "Transgenic knockout mice exclusively e 240-kb β-globin yeast artificial chromosome: A mouse <i>Sci. USA</i> 95:14886-14890 (1998)	expressing human hemoglobi e model of sickle cell anemia"	n S after transfer of a , <i>Proc. Natl. Acad.</i>	
	Chumakov et al., "A YAC contig map of the human ge	enome", <i>Nature</i> 377:175-297	(1995)	
	Cohen et al., "A first-generation physical map of the h	uman genome", Nature 336:	698-701 (1995)	
	Cole-Strauss et al., "Correction of the mutation respondigonucleotide," Science 273:1386-1389 (1996)	nsible for sickle cell anemia b	y an RNA-DNA	
*	Couch et al., "Mutations and Polymorphisms in the Fa Hum. Mutat. 8:8-18 (1996)	nmilial Early-Onset Breast Ca	ncer (BRCA1) Gene",	
	Crystal, Ronald G., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," <i>Science</i> 270: 404-410 (1995) Culver et al., "Correction of chromosomal point mutations in human cells with bifunctional oligonucleotides," <i>Nat. Biotechnol.</i> 17:989-993 (1999)			
	Ford et al., "Genetic Heterogeneity and Penetrance A Cancer Families", Am. J. Hum. Genet. 62: 676-689 (1	nalysis of the BRCA1 and BF 998)	RCA2 Genes in Breast	
	Gamper et al., "A plausible mechanism for gene corre 39(19): 5808-16 (2000)	ction by chimeric oligonucleo	tides," <i>Biochemistry</i>	
	Gamper et al., "The DNA strand of chimeric RNA/DNA repair/conversion activity in mammalian and plant cell (2000)	A oligonucleotides can direct -free extracts," <i>Nucleic Acids</i>	gene Res. 28:4332-4339	
	Gnirke et al., "Microinjection of Intact 200- to 500kb Fragments of YAC DNA into Mammalian Cells", Genomics 15:659-667 (1993) Igoucheva et al., "Targeted gene correction by small single-stranded oligonucleotides in mammalian cells," Gene Therapy 8:391-399 (2001)			
	Kaji et al., "Gene and Stem Cell Therapies," JAMA 28	5(5): 545-550 (2001)		
	Kmiec et al., "Targeted gene repair in mammalian cell Cold Spring Harbor Monograph Series 36: 643-670 (1		ligonucleotides,"	
	Knijff et al., "Genetic Heterogeneity of Apolipoprotein Lipoprotein Levels", <i>Hum. Mutat.</i> 4:178-194 (1994)	E and Its Influence on Plasma	a Lipid and	
	Kren et al., "Correction of the UDP-glucuronosyltransf Crigler-Najjar syndrome type I with a chimeric oligonu 10354 (1999)	erase gene defect in the Gun cleotide," <i>Proc. Natl. Acad.</i> S	n rat model of ci. USA 96:10349-	
	Kunzelmann et al., "Gene targeting of CFTR DNA in C	CF epithelial cells," Gene The	r. 3:859-867 (1996)	

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EXAMINER INITIAL				
	Liu et al., "In vivo gene repair of point and frameshift oligonucleotides and modified single-stranded oligon (2001)			
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	Spain et al., "Truncated BRCA2 is cytoplasmic: Impli Acad. Sci. USA 96:13920-13925 (1999)	cations for cancer-linked muta	tions", <i>Proc. Natl.</i>	
	Tizzano et al., "Cystic fibrosis: Beyond the gene to the	nerapy", <i>J. Pediat.</i> 120: 337-349	9 (1992)	
	Vasquez et al., "Chromosomal mutations induced by cells," <i>Nucl. Acids Res.</i> 27:1176-1181 (1999)	triplex-forming oligonucleotide	s in mammalian	
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	Woolf et al., "Toward the therapeutic editing of mutated RNA sequences," <i>Proc. Natl. Acad. Sci. USA</i> 92: 8298-8302 (1995)			
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	Yu et al., "An efficient recombination system for chro Natl. Acad. Sci USA 97:5978-5983 (2000)	mosome engineering in Esch	nerichia coli", Proc.	